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February 10, 2003

Ms. Mihn Thomas
Select Agent Program
Centers for Disease Control and Prevention
1600 Clifton Road, MS E-29
Atlanta, GA 30333

Dear Ms. Thomas:

The American Society for Clinical Pathology (ASCP) appreciates the opportunity to provide comments regarding the interim final rule for Possession, Use, and Transfer of Select Agents, as published in the *Federal Register* on December 13, 2002.

The American Society for Clinical Pathology (ASCP) is a nonprofit medical specialty society representing 150,000 members, including board certified pathologists, other physicians, clinical scientists, medical technologists and technicians. It is the world's largest organization representing pathology and laboratory medicine. As the leading provider of continuing education for pathologists and medical laboratory personnel, ASCP has suggestions regarding the clarity of select agent handling instructions for clinical and diagnostic laboratories, as presented in the interim final rule.

With regard to section 73.6(a), "Exemption Regarding Diagnosis, Verification, or Proficiency Testing," clarification is needed regarding reporting requirements for clinical and diagnostic laboratories upon diagnosis or verification of select agents. The regulation currently includes a subset of select agents that require immediate notification to the Department of Health and Human Services (HHS) upon diagnosis or verification. However, the rule fails to set forth instructions for HHS notification upon identification of the remaining select agents. The rule should be clarified to include specific notification timelines and methodologies for all select agents identified by the Secretary.

The rule, under the same section, also establishes timelines for the destruction or transfer of select agents discovered or verified in exempt clinical and diagnostic laboratories. The rule states that entities must transfer or destroy "those select agents or toxins used for diagnosis or verification within seven calendar days after identification, unless directed otherwise by the Federal Bureau of Investigation (FBI) or other law enforcement entity after consultation with the HHS Secretary."

As entities must notify HHS in writing at least five business days prior to select agent destruction, and only seven days post-identification are allotted for agent destruction or transfer, laboratories may experience difficulty adhering to the current regulatory timetable. For example, to stay within the 7-day timeline, entities will only have, at most,

two days from the time of identification to notify HHS of their intentions to destroy or transfer select agents. Depending on the burden of the notification process, entities may not be able to meet this deadline. Additionally, it is unclear whether entities will be required to wait for FBI or HHS decisions regarding disposal of the agent prior to initiating transfer or destruction. If this is the case, HHS will need to implement a rapid review process for destruction notifications in order to ensure laboratories are able to meet the 7-day deadline. Such a rapid review will also be necessary to ensure that entities do not destroy select agent samples, which may have been useful to the FBI or other government agencies investigating bioterrorist events, in order to meet the 7-day deadline.

The Centers for Disease Control and Prevention has specifically requested comment on the sufficiency of the 7-day and 90-day requirements for the transfer or destruction of select agents or toxins after identification. The sufficiency of the 7-day requirement will be determined by clarifications made to the HHS notification processes for identification and destruction or transfer. The longer, 90-day destruction or transfer deadline imposed for proficiency testing samples should allow laboratories sufficient time to ensure compliance.

Thank you for the opportunity to comment on the interim final rule for possession, use, and transfer of select agents. If you have questions, or need additional information, please give me a call or contact Rachel Juhas, ASCP Manager of Public Health Affairs, at (202) 347-4450.

Sincerely,

E E Baillie MD

E. Eugene Baillie, MD, FASCP
President